IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit 1793	:	
	:	
Application Serial No. 10/656,918	:	
	:	COBALT-NICKEL-CHROMIUM-
In re Application of Forbes Jones et al.	:	MOLYBDENUM ALLOYS WITH
	:	REDUCED LEVEL OF
Filed September 5, 2003	:	TITANIUM NITRIDE
	:	INCLUSIONS
Examiner Jessee Roe	:	

VIA EFS-Web

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 C.F.R. § 41.41

December 11, 2009

Sir:

Appellant submits this Reply Brief under 37 C.F.R. § 41.41 in response to the Examiner's Answer mailed on October 13, 2009 in connection with the pending appeal in the above-identified patent application (the "Subject Application"). Appellant respectfully requests entry and consideration of this Reply Brief.

I. STATUS OF CLAIMS

The Present Application was originally filed with claims 1-49. During prosecution, new claims 50-54 were added and claims 3, 9, 11, 21-31, 31 (inadvertent second occurrence), and 35-52 were cancelled. Claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 remain pending in the Present Application and form the basis of the present Appeal.

In the Final Office Action mailed August 18, 2008 (hereinafter "the Final Office Action"), claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 were rejected under 35 U.S.C. § 103(a) as having been obvious over U.S. Patent No. 3,356,542 to Smith (hereinafter "Smith"). Also, in the Final Office Action claims 13-15 were rejected under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 4,820,485 to Ototani et al. (hereinafter "Ototani"). In addition, in the Final Office Action, claims 20, 32-34, and 54 were rejected under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of U.S. Patent No. 6,342,068 to Thompson ("hereinafter "Thompson").

Accordingly, claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 stand rejected and are the subject of this appeal.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 under § 103(a) as having been obvious over Smith. Appellant submits that the Examiner did not establish a *prima facie* case of obviousness based on Smith.

2. The rejection of claims 13-15 under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of Ototani. Appellant submits that the Examiner did not establish a *prima facie* case of obviousness based on Smith in view of Ototani.

3. The rejection of claims 20, 32-34, and 54 under § 103(a) as having been obvious over Smith as applied to claim 1, and further in view of Thompson. Appellant submits that the Examiner did not establish a *prima facie* case of obviousness based on Smith in view of Thompson.

4. The Examiner's conclusion that the evidence of record of the secondary considerations of long-felt and unmet need, surprising and unexpected results, and/or commercial success did not rebut any *prima facie* case of obviousness that the Examiner did establish against any of the pending claims. Appellant submits that the evidence of secondary consideration of nonobviousness was sufficient to rebut any *prima facie* case of obviousness that may have been established.

III. ARGUMENTS

In a Final Office Action mailed August 18, 2008, the Examiner maintained his earlier rejection of claims 1, 2, 4-8, 10, 12, 16-20, and 32-34 under § 103(a) as having been obvious over the cited references. Of these rejected claims, claims 1 and 32 are the independent claims.

Appellant filed an Appeal Brief under 37 C.F.R § 41.37 on July 2, 2009, discussing the pending rejection of claims 1, 2, 4-8, 10, 12, 16-20, and 32-34 under § 103(a) and demonstrating that these claims were not shown to have been obvious in view of the cited references. On October 13, 2009, an Examiner's Answer (the "Answer") was issued in response to the Appeal Brief. Appellant submits that the Answer includes a number of assertions that are factually incorrect, legally incorrect, or both. Appellant addresses these incorrect assertions below. All references herein to the Specification of the Present Application refer to the page and line numbers of the Specification as originally filed, not as published.

A. The Overlap Between Smith and Present Claim 1 is Insignificant and, for at least that reason, Smith Does Not Teach or Suggest the Compositional Limitations of the Alloy Recited in Claim 1.

In the Answer, the Examiner argues that the overlap between the alloy composition recited in the claims under appeal and Smith establishes a *prima facie* case that the claimed alloy would have been obvious. The Examiner seeks to establish that the overlap exists by providing, for example, the chart on the top of page 12 of the Answer listing the weight percentage range of overlap between the "Instant Claims" and Smith. Appellant does not contend that overlap does not exist here. Considering only the weight percentage range of the overlap, however, is misleading. One must also consider the relative degree of the overlap. Here, the Examiner fails to point out the insignificance of the overlap when several of the elemental ranges recited in the claims are considered relative to the ranges described in Smith. In fact, many of the elemental

ranges described in Smith are many times greater than the overlap between the elemental ranges. Appellant asks that the Board consider the following:

Nickel – Smith teaches an alloy having 5 to 45 weight percent nickel, which is a range of 40 weight percent. Present claim 1 recites 32.7 to 37.3 weight percent nickel, which is a range of only 4.6 weight percent. The nickel range taught by Smith is approximately **870% greater** than the overlap between the Smith range and present claim 1.

Chromium – Smith teaches an alloy having 13 to 25 weight percent chromium, which is a range of 12 weight percent. Present claim 1 recites 18.75 to 21.25 weight percent chromium, which is a range of only 2.5 weight percent. The chromium range taught by Smith is **480% greater** than the overlap between the range of Smith and present claim 1.

Molybdenum – Smith teaches an alloy having 7 to 16 weight percent molybdenum, which is a range of 9 weight percent. Present claim 1 recites 8.85 to 10.65 weight percent molybdenum, which is a range of only 1.8 weight percent. The molybdenum range taught by Smith is **500% greater** than the overlap between the range of Smith and present claim 1.

Nitrogen – The Examiner takes the position that Smith teaches an alloy having 0 up to 0.05 weight percent (500 ppm) of nitrogen, which is a range of 500 ppm.[1] Present claim 1 recites less than 30 ppm nitrogen, which is a range of only somewhat less than 30 ppm. Assuming only for argument's sake that Smith does teach a range of 500 ppm nitrogen, that range is approximately 1670% greater than the overlap between the range of Smith and present claim 1.

[1] As discussed in the Appeal Brief, Appellant submits that Smith does not suggest a range of nitrogen that is any lower than the 50 ppm nitrogen concentration that is the minimum nitrogen concentration in a conventional MP35N alloy. *See, e.g.,* Appellant's arguments at pages 20-21 of the Appeal Brief. Nevertheless, Appellant applies the Examiner's position on the nitrogen range taught by Smith only to demonstrate the insignificance of degree of overlap if the Board adopts the Examiner's position.

Iron - Smith teaches an alloy having 0 to 6.0 weight percent iron, which is a range of 6 weight percent. Present claim 1 recites less than 1.05 weight percent iron, which is a range of only 1.05 weight percent. The iron range taught by Smith is approximately **570% greater** than the overlap between the range of Smith and present claim 1.

Below is an annotated version of the Examiner's chart from page 12 of the Answer, supplemented with a column indicating the relative insignificance of the degree of overlap between the nickel, chromium, molybdenum, nitrogen, and iron ranges taught in Smith and the ranges recited in present claim 1.

Element	**From Instant Claims** (weight percent)	**Smith ('542)** (weight percent)	**Overlap** (weight percent)	**Size of Smith Range Relative to Overlap**
Co	At least 20	At least 25	At least 25	
Ni	32.7-37.3	5-45	32.7-37.3	**870%**
Cr	18.75-21.25	13-25	18.75-21.25	**480%**
Mo	8.85-10.65	7-16	8.85-10.65	**500%**
N	Less than 30 ppm	0-0.05	Less than 30 ppm	**1670%**
Ti	Less than 0.7	0-2.0	Less than 0.7	
Al	At lest 0.05	0-2.0	0.05-2.0	
Fe	Less than 1.05	0-6.0	Less than 1.05	**570%**

The Examiner's argument regarding overlap and the charts the Examiner uses to support that argument greatly oversimplify the issue and are misleading because they do not consider the relative breadth of the ranges. In fact, the overlap here between the broad elemental ranges described in Smith and the relatively very narrow ranges recited in the present claims for nickel, chromium, molybdenum, and nitrogen, is so insubstantial that the Examiner cannot reasonably assert that Smith discloses or renders obvious the alloy recited in the present claims. *See* MPEP § 2131.03 ("If the claims are directed to a narrow range, [and] the reference teaches a broad range, ... [i]t may be reasonable to conclude that the narrow range is not

disclosed with 'sufficient specificity' to constitute an anticipation of the claims."; *Atofina v. Great Lakes Chem. Corp*, 441 F.3d 991, 999 (Fed. Cir. 2006) ("Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim.").[2]

Therefore, a *prima facie* case of obviousness of claim 1 has not been established based on Smith.

B. In Seeking to Modify the Alloy of Smith, One of Ordinary Skill Would Not Have Sought to "Optimize" the Claimed Ranges of Nitrogen and Four Other Elements.

Appellant has shown that the overlap between the broad alloy composition described in Smith and the relatively very narrow and specific alloy composition recited in present claim 1 is insubstantial. In the Answer, the Examiner suggests that the rejections are nevertheless appropriate because one would have been motivated to optimize the broad composition described in Smith and achieve the alloy composition recited in the present claims. On page 16 of the Answer, for example, the Examiner essentially argues that because "the normal desire of scientists or artisans to approve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", one of ordinary skill in the art (without knowledge of the present invention) would have optimized the up to 0.05 weight percent (*i.e.*, up to 500 ppm) nitrogen range in Smith to the claimed range of less than 30 ppm nitrogen.

[2] The Examiner has argued that the *Atofina* decision applies to rejections based on anticipation, but not to obviousness rejections. As explained in footnote 1 of the Appeal Brief, Appellant disagrees and submits that *Atofina* more fundamentally addresses how a prior art reference disclosing a range may be applied in an art-based rejection. In any case, to the extent that the Board may view the rejections here as anticipation rejections, the applicability of *Atofina* is uncontested, and the very insubstantial nature of the overlap here, evidenced by the comments and chart above, precludes maintaining the rejections.

Appellant disagrees that any desire to "optimize" the alloy composition of Smith would have led one to the alloy composition recited in claim 1. Here, considering the chart above, one would have had to "optimize" no less than five relatively broad elemental ranges to arrive at the much narrower ranges that are recited in claim 1 of the Present Application. The Examiner, however, has not even properly identified any features or characteristics as being a result effective variable to which the ranges should be optimized, or otherwise articulated sufficient reasoning as to why one of ordinary skill in the art, with no knowledge of the present invention, would have sought to optimize any particular elemental range, let alone five elemental ranges. As required under MPEP § 2144.05(II)(B), "[a] particular parameter must first be recognized as a result-effective variable, *i.e.*, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation." (Citing *In re Antonie*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Also, the Smith reference teaches that "it is critically important that the alloy composition contain no more than 0.05% of carbon, boron, oxygen, nitrogen or beryllium ....", thereby setting a maximum amount not only for nitrogen, but also for 4 other elements. One of ordinary skill in the art, without knowledge of the present invention and without knowing that titanium nitrides and mixed metal carbonitride inclusions are of concern (a discovery of the present inventors), would have no more incentive to investigate criticalities associated with (*i.e.*, optimizing) nitrogen than with any of carbon, boron, oxygen, or beryllium. The Examiner has not provided any reasoning as to why one would have sought to optimize nitrogen over the other trace elements in that list. *See* MPEP § 2144.05(II)(B).

In addition, on page 18 of the Answer, the Examiner points out that the Smith reference discloses a composition having no more than 2% of titanium and no more than 0.05 wt.% of carbon. From this, the Examiner essentially argues that the Smith composition "could" completely lack titanium and carbon and therefore would not include titanium nitride or mixed metal carbonitride inclusions regardless of nitrogen

content. This reasoning is impermissibly based purely on hindsight. Only with recognition that titanium nitride and mixed metal carbonitride inclusions are of concern would one select a composition within the broad disclosure of the Smith reference that would lack both titanium and carbon, even if nitrogen were present.

Accordingly, the Examiner's arguments that one would have been motivated to optimize the Smith composition and achieve the claimed composition are unreasonable.

C. The Examiner Cannot Rely on a Theory of Inherency to Satisfy Microstructural Limitations Recited in Present Claim 1.

In order to properly formulate a rejection under § 103(a), all of the claim elements and limitations must be taught or suggested by the cited prior art. Here, in addition to reciting an elemental composition, present claim 1 also recites certain microstructural characterisitics of the alloy. Specifically, claim 1 recites that that the alloy "includes generally spherical oxide inclusions and is substantially free of titanium nitride and mixed metal carbonitride inclusions." However, the Examiner concedes that Smith does not disclose that its alloy has or may have those microstructural characterisitcs. For example, on page 12 of the Answer the Examiner concedes that Smith "does not specify wherein the alloy would include spherical oxide inclusions and would be substantially free of titanium nitride and mixed metal carbonitride inclusions." In an attempt to fill in this gap in the cited prior art and establish a *prima facie* case of obviousness, the Examiner makes the following argument in the Answer:

> Additionally, Smith ('542) does not specify that the alloy would include spherical oxide inclusions and would be substantially free of titanium nitride and mixed metal carbonitride inclusions. However, the presence of titanium, nitrogen, and carbon within the alloy can be non-existent as specified by Smith ('542) (col. 4, line 69 - col. 5, line 11). Further, Smith ('542) discloses arc melting and induction melting in a vacuum atmosphere as methods of preparing the alloy, which would be substantially the same techniques of producing the alloys of the instant invention (col. 4, lines 23-42 and col. 5, lines 11-30). Therefore, it

> would be expected that the alloys of Smith ('542) would have generally spherical oxide inclusions and be substantially free of titanium nitride and mixed metal carbonitride inclusions. MPEP 2112.011.

Answer at p. 12.

In other words, the Examiner argues that the recited microstructural characteristics in claim 1 regarding the presence and absence of certain inclusions would have been inherent in the alloy described in Smith. (MPEP § 2112 is directed to inherency.) However, a fundamental flaw in the Examiner's argument is that inherency is not an appropriate basis for a rejection under § 103(a). As set forth in MPEP § 2141.02(V), "obviousness cannot be based on what is not known at the time an invention is made, even if the inherency of a certain feature is later established." In other words, an obviousness rejection cannot be based on a theory of inherency. Rather, in order to rely on some allegedly inherent feature of the prior art when establishing an obviousness rejection, the allegedly inherent feature must have been taught or suggested in the prior art at the time that the claimed invention was made. *In re Rijckaert*, 9 F.3d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993).

In the case *In re Rijckaert*, the patent examiner based an obviousness rejection on a combination of prior art references that failed to teach or suggest certain features recited in the rejected claims. *Id.* The Examiner argued that these features would have been inherent in the combined disclosures of the prior art and that a person skilled in the art would understand the features to be inherent. *Id.* The Federal Circuit reversed the examiner's legal conclusion of obviousness, stating that, as a matter of law, "a retrospective view of inherency is not a substitute for some teaching or suggestion supporting an obviousness rejection." *Id.* The Court held that obviousness cannot be shown based on what is not known in the prior art at the time an invention is made, even if the inherency of a certain feature is later established. *Id.; see also* MPEP § 2141.02.V.

Thus, the law governing obviousness under § 103(a) requires that allegedly inherent features be taught or suggested in the prior art in order to support a case of *prima facie* obviousness. This well-settled principle of law is supported by a number of cases. *See, e.g., In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966) ("...the inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown."); *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555, 220 USPQ 303, 314 (Fed. Cir. 1983) ("Inherency and obviousness are distinct concepts."); *Kloster Speedsteel AB v. Crucible Inc.*, 793 F.2d 1565, 1576, 230 USPQ 81, 88 (Fed. Cir. 1986) (an inherent feature may be relied upon to establish obviousness only if the inherency would have been obvious to a person skilled in the art); *Cohesive Technologies Inc. v. Waters Corp.*, 543 F.3d 1351, 88 USPQ2d 1903 (Fed. Cir. 2008) ("... although anticipation can be proven inherently, proof of inherent anticipation is not the same as proof of obviousness."). Indeed, this principle of law is so well-settled that it is stated in a preeminent treatise on United States patent law. *See* 2 Donald S. Chisum, *Chisum on Patents* § 5.03[3][a][i][A] (Matthew Bender) (a single prior art reference may anticipate because of the inherent disclosure of the reference, but inherent disclosure may only be used to support obviousness if the inherent subject matter itself would have been obvious, *i.e.*, taught or suggested in the prior art).

In addition, in the case of *In re Newel,* 891 F.2d 899, 13 USPQ2d 1248 (Fed. Cir. 1989), the patent examiner based an obviousness rejection on a combination of prior art references that failed to teach or suggest certain features recited in the rejected claims, arguing that the missing subject matter would have been inherent in the prior art. Again, the Federal Circuit reversed the examiner's legal conclusion of obviousness, holding that, as a matter of law, an examiner cannot use an unsupported inherency argument as an end-run around the requirement for a teaching or suggestion of the asserted inherent feature in the prior art. *Id.* The Court held that additional extrinsic prior art evidence is required to support an asserted inherency argument in an obviousness rejection. *Id.*

Thus, the case law holds that obviousness rejections based on asserted "inherent" properties in the art cannot be sustained when there is no teaching or suggestion in the prior art to support the assertedly inherent subject matter. *In re Spormann, supra; In re Rijckaert, supra.* When a patent examiner asserts that there is a recited feature inherent in the prior art, the examiner must produce supporting references from the prior art that factually teach or suggest the allegedly inherent subject matter. *In re Newell, supra.*

In the present case, the Examiner has failed to cite to any references or other prior art evidence that teaches or suggests that the compositional and processing features described in Smith would inherently result in the microstructural characteristics regarding inclusions recited in claim 1. Therefore, the cited references do not establish a *prima facie* case that the subject matter of claim 1 would have been obvious under § 103(a).

Moreover, to establish inherency in any case, the extrinsic evidence (*i.e.*, the cited references) must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be recognized as such by a person skilled in the art. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999); MPEP § 2112.IV. Inherency may not be established by probabilities or possibilities; instead, inherency requires factual evidence of an alleged inherent feature. *Id.* In this regard, MPEP § 2112.IV provides that:

> In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

Accordingly, in order for the inclusion characteristics recited in claim 1 to have been inherent, as asserted by the Examiner, these characteristics must necessarily exist in the subject matter described in Smith. However, the inventors in the Subject Application showed that the inclusions characteristic of the alloy recited in claim

1 are due, at least in part, to the compositional relationship recited in claim 1 which, as discussed above and in the Appeal Brief, is not taught or suggested in Smith.

Therefore, the Examiner's unsupported assertion that the microstructural characteristics recited in claim 1 would have been inherent is an entirely conclusory statement that cannot form the basis of a *prima facie* case under 35 U.S.C. § 103(a).

D. Applicants' Submitted Evidence Established that the Claimed Invention Exhibited Surprising and Unexpected Results.

1. The Examiner's Reference to Fatigue Results at 250 ksi does not Detract from the Showing of Unexpected Results.

On page 37-42 of the Appeal Brief, Appellant demonstrates that the Subject Application and the Lippard Declaration provided detailed and uncontradicted evidence that the claimed invention provided surprising and unexpected fatigue resistance properties. On page 13 of the Answer, the Examiner argues that the evidence did not establish unexpected results for the following reason:

> In response, the Examiner notes (see Table 9) that the standard MP35N alloy has an improved fatigue resistance over modified MP35N alloy at a stress value of 250 ksi. At 250 ksi standard MP35N alloy withstood 116% (11,129/9,586) the number of cycles in rotary beam fatigue testing than wire produced from modified MP35N alloy. Therefore, the modified MP35N alloy would not patentably distinguish from the conventional MP35N alloy.

Initially, Appellant notes that this is the first time that the Examiner has put forth this argument or any specific argument as to why he considers the showing of unexpected results unconvincing. This is the case even though the Lippard Declaration was submitted to the Office on August 27, 2007, and the issue whether unexpected results have been demonstrated has been before the Office for several years. In any case, for at least the following reasons, the fact that a sample of conventional MP35N alloy wire withstood 116% the number of cycles in the rotary beam testing than a

sample of modified MP35N alloy wire when tested at 250 ksi does not disprove that the modified alloy exhibited unexpected results.

First, the small difference between the numbers of cycles achieved by the conventional and modified MP35N alloy samples at 250 ksi arguably was not so significant as to be statistically meaningful. In contrast, the difference in number of cycles achieved by the modified alloy relative to the conventional alloy at 100 ksi was at least 797%, which is substantially more and, it is submitted, could not be adjudged statistically insignificant.

Second, all of the evidence of unexpected results should be considered, without focusing on any particular result as being determinative. Many other test results established that the modified MP35N alloy produced unexpected results relative to the conventional alloy. For example, in addition to the very substantial differential in cycles achieved by the modified MP35N alloy sample in rotary beam fatigue testing at 100 ksi, the specification of the Present Application explains that the endurance limit of the conventional MP35N alloy sample was 90 ksi, while the endurance limit of the modified MP35N sample was between 100 and 110 ksi and the sample withstood a runout at 100 ksi. *See* Present Application at paragraph [0070]-[0071]. Moreover, the inclusions found in the modified MP35N alloy in microcleanliness testing described in the Present Application were significantly smaller, substantially less numerous, and had a rounded morphology relative the conventional MP35N alloy. *See* paragraphs [0058]-[0063] and Table 6.[3] Also, Table 9 of the Present Application clearly shows that the differential in number of cycles between the modified and conventional alloy samples before wire breakage in rotary beam testing increased very substantially as the stress applied to the

[3] Of course, this observation is of particular significance given the inventors' discovery that inclusions were responsible for sub-par mechanical performance of conventional MP35N alloy.

samples was decreased from 250 ksi to 90 ksi.[4] As explained in paragraph [0069] of the Present Application:

> Beginning with a relatively high stress level of 200 Ksi, the improvement achieved by the experimental low-titanium alloy is evident. The improvement continues and is most dramatic nearer the 100 ksi stress level, which is considered to represent the actual in-use range for surgical implants such as pacing leads.

In short, the test results discussed in the Present Application, viewed as a whole, provide a compelling case for surprising and unexpected results, and considering one result in isolation is misleading.

Third, evaluating fatigue resistance of conventional and modified MP35N alloy samples by rotary beam fatigue testing at 100 ksi is substantially more meaningful to assessing whether an alloy exhibits unexpected results given that 100 ksi is a stress level representative of the actual in-use stress to which surgical implants such as pacing leads are subjected in the human body. *See, e.g.,* paragraph [0069] of the Present Application. What better test conditions could have been developed to assess the significance of an improvement in the properties of an alloy adapted for use in surgical implants? In contrast, the fatigue resistance properties of the alloys at 250 ksi is not relevant to assessing alloy performance in surgical implant applications. Moreover, as discussed in paragraph 11 of the Lippard Declaration, reproduced below, the fatigue endurance limit of the modified alloy was between 100 and 110 ksi, while that of the conventional alloy was only 90 ksi. Given that the endurance limit represents the stress level at which a sample theoretically can withstand an infinite number of cycles in rotary beam testing without failure, and given that the 100 ksi level is representative of the in-

[4] As explained in paragraph [0068] of the Present Application, in Figure 9 the 54,000,000 cycles withstood by the modified MP35N alloy at a stress level of 100 ksi without wire breakage was considered a "runout" and showed that the material could theoretically withstand an infinite number of cycles at that stress level. Because the modified MP35N alloy sample withstood a runout at 100 ksi, it followed that material also would have withstood a runout at lower stress levels. Therefore, as reflected in Table 9, the modified MP35N alloy was not tested at 90 ksi.

use stress level, the comparative endurance limit of the alloys are very significant and meaningful evidence of unexpected results.

> 11. As discussed in detail in the Application, an apparent result of the above-discussed fundamentally different microstructure of the small-diameter wire produced from the alloy described in the Application exhibits very substantially improved fatigue resistance relative to conventional MP35N alloy. Table 9 of the Application, for example, shows that at 100 ksi, a stress level similar to that to which cardiac pacemaker leads are subjected in service (*i.e.*, implanted in the body), wire formed from the alloy described in the Application withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy, and the modified alloy had a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of the conventional alloy. This improvement in fatigue properties was very significant, was surprising to me and my co-inventors, and was not expected even after we observed the fundamentally altered microstructure of the alloy of the Application. The unexpectedly significantly improved fatigue resistance of the modified alloy directly addressed the above-mentioned long felt need in the medical device industry for a biocompatible MP35N-type alloy useful for pacemaker leads and other surgically implanted components having a reduced incidence of fatigue-induced fracture.

Fourth, even if the modified MP35N alloy sample withstood less cycles in rotary beam fatigue testing at 250 ksi that the conventional alloy sample, it is still possible that the modified alloy sample has significantly better fatigue properties evaluated at 100 ksi and an endurance limit significantly greater than the conventional alloy. In other words, the Examiner's observation regarding relative fatigue properties evaluated by rotary beam fatigue testing at 250 ksi does not cast any significant doubt on the technical accuracy of the remaining test results, discussed above.

For the first time during the prosecution of the Present Application the Examiner apparently argues that because the number of cycles before breakage observed in rotary beam fatigue testing at 250 ksi fatigue was greater by a small degree

for conventional MP35N alloy than modified MP35N alloy, the Examiner may conclude that the showing of unexpected results is unconvincing. However, Appellant respectfully submits that the 250 ksi fatigue results are simply a "red herring" – the 250 ksi results do not detract from the substantial weight of the showing of unexpected results when the evidence is properly viewed as a whole. When properly considered, the modified MP35N alloy clearly and substantially outperformed the conventional alloy.

Appellant also wishes to address one additional point the Examiner raises for the first time in the Answer. On page 26 of the Answer, the Examiner states as follows:

> Since the pending claims do not recite a stress value or range of stress values applied to the alloy for which the fatigue resistance of the modified MP35N alloy is greater than the fatigue resistance of the conventional MP35N alloy there are stress values (i.e. 250 ksi) where standard MP35N alloy has better properties than modified MP35N alloy, the modified MP35N alloy would not patentably distinguish from the conventional MP35N alloy.

Thus, the Examiner apparently concludes that if the pending claims did recite, for example, that the claimed alloy exhibits improved fatigue resistance at 100 ksi versus conventional MP35N alloy, then the claims would be patentable. Appellant disagrees. Patentability here does not require that the claims recite particular conditions under which surprising and unexpected results are achieved. Instead, Applicants simply submitted the evidence of surprising and unexpected results to rebut any *prima facie* case of obviousness that may have been established.

For the reasons set forth in the Appeal Brief and in the present Reply, Appellant respectfully submits that any *prima facie* case of obviousness that may have been established has been rebutted by Applicant's showing of surprising and unexpected results. Accordingly, the pending claims should have been held patentable over the references of record.

2. Applicants' Showing of Unexpected Results Compared the Modified MP35N Alloy to the Closest Prior Art Alloy.

In the Answer, the Examiner argues that the showing of unexpected results was not sufficient because Applicants did not meet the burden of establishing the criticality of the range of less than 30 ppm nitrogen over the range of 500 ppm (*i.e.*, 0 to 0.05 weight percent) nitrogen the Examiner asserts is disclosed in Smith. *See* pages 13, 14, 16, and 18 of the Answer. Appellant disagrees. In fact, the working examples of the Present Application include data comparing standard MP35N alloy (which is described in paragraph [0033] of the Present Application as including at least about 50 ppm nitrogen) with modified MP35N alloy satisfying the limitations of present claim 1. Applicants believe conventional MP35N alloy to be the closest prior art alloy. What better comparative test data could have been submitted to establish that surprising and unexpected results were achieved? The comparative fatigue test data and microcleanliness observations for the conventional and modified alloys demonstrate the clear superiority of the modified alloy.

Accordingly, it should be held that the evidence submitted, including the evidence set forth in the Present Application and in the Lippard Declaration, was sufficient to establish that the claimed invention provided surprising and unexpected results.

IV. CONCLUSION

For the reasons discussed above and in the Appeal Brief, Appellant respectfully submits that the Examiner has not established a *prima facie* case of obviousness as applied to any of the pending claims. Moreover, even if such a case was established, Appellant respectfully submits that the evidence of secondary considerations submitted to the Examiner was sufficient to rebut any established case of obviousness.

Accordingly, Appellant respectfully requests that the Examiner be directed to: (1) reverse the § 103(a) rejection of 1, 2, 4-8, 10, 12, 16-20, 32-34, 53, and 54 over Smith; (2) reverse the § 103(a) rejection of claims 13-15 over Smith as applied to claim 1, and further in view of Ototani; (3) reverse the § 103(a) rejection of claims 20, 32-34, and 54 over Smith as applied to claim 1, and further in view of Thompson; and (4) allow all claims currently ending in the Present Application.

Respectfully submitted,

December 11, 2009

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